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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/588,637	01/19/96	BARBOUR	A 454312-2420

18M1/0709 EXAMINER
SIDBERRY, H

WILLIAM S FROMMER
CURTIS MORRIS & SAFFORD
530 FIFTH AVENUE
NEW YORK NY 10036

ART UNIT PAPER NUMBER

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on _____

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-12 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Claims 1-12 are pending and under examination.

The disclosure is objected to because of the following informalities: The drawings are objected to under 37 CFR 1.84 for the reasons set forth on the PTO form 948. The specification is 5 objected to because the reference to "Becker et al U.S. Application Serial No." is incomplete.. The specification also should be checked for typographical errors, see for example page 3, 2nd line from the bottom where "PRC/US92/08697" is cited. Appropriate correction is required.

10 A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to 15 identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they 20 are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 11, 12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims of copending 25 application Serial No. 08 375 993 (allowed but not issued) (directed to the composition). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 11, 12 are rejected under 35 U.S.C. § 102(e) as being 30 anticipated by 08 375 399.

Claims 11, 12 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending application Serial No. 08 373 455 which has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the copending 5 application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application. 08 375 399 (allowed but not issued).

This provisional rejection under Section 102(e) might be overcome 10 either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

15 The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 20 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

25 A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

30 Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

35 Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim of copending application Serial No. 08 375 993 (allowed but not issued) Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed to "mucosally" administering OspA

and a composition of OspA. 08/375 399 is directed to a composition of OspA and a method of administering which is not defined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5 Claims 1-12 are provisionally rejected under 35 U.S.C. § 103 as being obvious over copending application Serial No. 08/375 399.

Copending application Serial No. 08/375 399 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would 10 constitute prior art under 35 U.S.C. § 102(e) if patented. This provisional rejection under 35 U.S.C. § 103 is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 C.F.R. § 1.132 that any unclaimed invention 15 disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention prior to the effective U.S. filing date of the copending application under 37 C.F.R. § 1.131.

20 Claims 1-12 are rejected under 35 U.S.C. § 103 as being unpatentable over allowed 08/375 399.

Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards 25 as the invention.

Claim 1 is vague and indefinite because of the use of an abbreviation in the claim, "OspA". It is suggested that full terminology be used, at least at the first occurrence of the term.

Claims 2 and 8 are vague and indefinite in the recitation of 30 "substantially free" of other bacteria proteins and LPS.

"Substantially" is a broad term (see In re Nehrenberg (CCPA) 126 USPQ 383. It is unclear what are the metes and bounds of "substantially free".

Claim 2 is indefinite because of the use of an abbreviation in 35 the claim, "LPS". It is suggested that full terminology be used, at least at the first occurrence of the term.

Claim 7 is vague and indefinite in the recitation of "consisting essentially". Consisting essentially limits the scope of the claim to the specified ingredients and those that do not

materially affect the basic and novel characteristics of a composition. Ex parte Davis, 80 US PQ 448 (PTO Bd. App 1948)

5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless--

10 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15 (b) the invention was patented or described in a printed publication in this country or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

25 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

30 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 40 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the

obligations under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) 5 prior art under 35 U.S.C. § 103.

Claims 1-4, 6-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bergstrom et al US Patent US Patent 5 523 089.

Bergstrom et al US Patent 5 523 089 disclose a method of 10 mucosal administration of recombinantly produced OspA. The OspA may be given in a solution, or tablets, optionally with no adjuvant. (see column 18, lines 31-35)

Claim 5 is rejected under 35 U.S.C. § 103 as being unpatentable over Bergstrom et al US Patent, in view of Flavell et 15 al WO 92/00055.

Bergstrom et al US Patent teach oral administration of a recombinant OspA, in a solution or tablet, but does not teach placing the OspA in "bait food".

However, Flavell et al WO 92/00055 suggest that OspA can be 20 placed in animal food. (see page 34, lines 16-26)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further administer OspA in animal food, with the expectation of inducing an immunological response in animals which serve as a reservoir for 25 the Lyme disease tick.

Claims 1-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Flavell et al WO 92/00055.

Flavell et al WO 92/00055 disclose a method of mucosally giving OspA which can be produced in E. coli. The OspA may be given 30 orally. Flavell et al disclose oral administration of OspA "with animal food" (see page 25, lines 16-30 page 33, lines 19, page 34, line 16-26)

Claims 11, 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Simon et al US Patent 5 178 859 or Wilske et al or 35 Benach et al or Fuchs et al PCT/EP90/02282.

Simon et al US Patent 5 178 859 disclose a composition of OspA

in a diluent which appears "suitable for oral administration".
(see at least the Abstract)

Benach et al (The Journal of Immunology 140:265-272, 1988)
disclose an OspA composition. (see Abstract, page 265)

5 Wilske et al (Annals of The New York Academy of Sciences
539:126-143, 1988) disclose OspA in solution. (see page 129, and
Figure 4 which shows the purified OspA)

Fuchs et al PCT/EP90/02282 (Translation of German document)
disclose a composition of OspA. (see pages 7, 23)

10 Any inquiry concerning this communication or earlier
communications from the examiner should be directed to H. Sidberry
whose telephone number is (703) 308-0170.

15 Any inquiry of a general nature or relating to the status of
this application should be directed to the Group receptionist whose
telephone number is (703) 308-0196.

Papers related to this application may be submitted to the
Group 1800 by facsimile transmission. The CM1 1802 fax Center number
is (703) 308-4227

20 Sidberry/hfs
July 1, 1997

H. Sidberry
SIDBERRY
EXAMINER
GPO: 1800